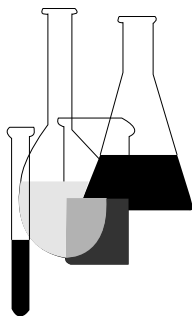




Ecological Effects Test Guidelines

OPPTS 850.2400

Wild mammal acute
toxicity



“Public Draft”

INTRODUCTION

This guideline is one of a series of test guidelines that have been developed by the Office of Prevention, Pesticides and Toxic Substances, United States Environmental Protection Agency for use in the testing of pesticides and toxic substances, and the development of test data that must be submitted to the Agency for review under Federal regulations.

The Office of Prevention, Pesticides and Toxic Substances (OPPTS) has developed this guideline through a process of harmonization that blended the testing guidance and requirements that existed in the Office of Pollution Prevention and Toxics (OPPT) and appeared in Title 40, Chapter I, Subchapter R of the Code of Federal Regulations (CFR), the Office of Pesticide Programs (OPP) which appeared in publications of the National Technical Information Service (NTIS) and the guidelines published by the Organization for Economic Cooperation and Development (OECD).

The purpose of harmonizing these guidelines into a single set of OPPTS guidelines is to minimize variations among the testing procedures that must be performed to meet the data requirements of the U. S. Environmental Protection Agency under the Toxic Substances Control Act (15 U.S.C. 2601) and the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136, *et seq.*).

Public Draft Access Information: This draft guideline is part of a series of related harmonized guidelines that need to be considered as a unit. *For copies:* These guidelines are available electronically from the EPA Public Access Gopher (gopher.epa.gov) under the heading “Environmental Test Methods and Guidelines” or in paper by contacting the OPP Public Docket at (703) 305-5805 or by e-mail: guidelines@epamail.epa.gov.

To Submit Comments: Interested persons are invited to submit comments. By mail: Public Docket and Freedom of Information Section, Office of Pesticide Programs, Field Operations Division (7506C), Environmental Protection Agency, 401 M St. SW., Washington, DC 20460. In person: bring to: Rm. 1132, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. Comments may also be submitted electronically by sending electronic mail (e-mail) to: guidelines@epamail.epa.gov.

Final Guideline Release: This guideline is available from the U.S. Government Printing Office, Washington, DC 20402 on *The Federal Bulletin Board*. By modem dial 202-512-1387, telnet and ftp: fedbbs.access.gpo.gov (IP 162.140.64.19), or call 202-512-0135 for disks or paper copies. This guideline is also available electronically in ASCII and PDF (portable document format) from the EPA Public Access Gopher (gopher.epa.gov) under the heading “Environmental Test Methods and Guidelines.”

OPPTS 850.2400 Wild mammal acute toxicity.

(a) **Scope**—(1) **Applicability.** This guideline is intended to meet testing requirements of both the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136, *et seq.*) and the Toxic Substances Control Act (TSCA) (15 U.S.C. 2601).

(2) **Background.** The source material used in developing this harmonized OPPTS test guideline is OPP 71-3 Wild Mammal Toxicity Test (Pesticide Assessment Guidelines, Subdivision E—Hazard Evaluation; Wildlife and Aquatic Organisms) EPA report 540/09-82-024, 1982.

(b) **When required**—(1) Data on the toxicity of a pesticide to wild mammals are required by 40 CFR 158.145 on a case-by-case basis to support the registration of an end-use product intended for outdoor application. The toxicity data required by 40 CFR 158.135 for evaluating hazards to humans and domestic animals are normally adequate to indicate hazard to wild mammals. Under certain conditions, however, these data are not sufficient to assess the potential hazard to wild mammals which are likely to be exposed to an end-use product. Examples of circumstances when data on the toxicity of a pesticide to wild mammals may be required by 40 CFR 158.145 include, but are not limited to, the following:

(i) When data (e.g. data required by 40 CFR 158.135) indicate that there is considerable variation in the sensitivity of different mammalian species to the toxic effects of a pesticide, and when there is evidence that wild mammals are heavily exposed to pesticides; and

(ii) When pesticides with bactericidal properties will be applied to the forage of wild ruminants, and toxicological data do not include information on possible interference with rumen fermentation in domestic (or wild) ruminants.

(2) See 40 CFR 158.50, ‘‘Formulators’ exemption,’’ to determine whether these data must be submitted. Section II-A of this Subdivision provides an additional discussion on this subject.

(c) **Test standards.** Data sufficient to satisfy the requirements in 40 CFR 158.145 should be derived from tests which comply with the general test standards in § 70-3 and all of the following standards:

(1) **Test substance**—(i) Generally, data should be derived from testing conducted with the technical grade of each active ingredient in the product.

(ii) In special circumstances, data from testing conducted with the applicant’s end-use formulation or a typical end-use product may be required by 40 CFR 158.75(b) to support the registration of an end-use product. Examples of such circumstances include, but are not limited to:

(A) When effects of the product on the rumen fermentation process need to be determined, or

(B) When secondary toxicity studies need to be performed (e.g. product is introduced into prey species which is fed to predator species).

(2) **Species.** Testing should be performed on a mammalian species representative of those found in the area(s) likely to be affected by the proposed use pattern(s). Test animals may be pen-reared or wild captured, but should be phenotypically indistinguishable from wild mammals. In no case should endangered or threatened animals be used for testing.

(3) **Toxicity determination.** When the animals are large or the species is relatively scarce, a study which determines only the approximate maximum tolerated dosage for the test species may be acceptable. In all other cases, the acute oral LD50, dietary LC50, or dietary no-effect level should be determined, following consultation between the Agency and the registrant.

(d) **Reporting and evaluation of data.** In addition to the information provided in § 70-4, test reports should contain the following information:

- (1) Age of each animal and how determined;
- (2) Mean body weight for each test and control group at initiation and termination of test;
- (3) Number of animals of each sex of animal tested;
- (4) Total food consumption for each test and control group;
- (5) Test diet;
- (6) Dose schedule;
- (7) Mortality;
- (8) Number and circumstances of accidental deaths or injuries;
- (9) LD50 (in mg/kg) or LC50 (in ppm) with 95 percent confidence limits, or estimated maximum tolerated dose;
- (10) Specified methods used to calculate LD50 or LC50; and
- (11) Slope of the dose-response line.

(e) **Acceptable protocols.** Because the Agency intends that toxicity tests on mammals, other than those required by 40 CFR 158.135, be conducted only to access specific situations, no single test methodology can provide adequate guidance for all cases. In addition, there are no widely accepted protocols that include husbandry practices appropriate to a diversity of mammals. Therefore, the test methodologies should be determined

on a case-by-case basis. Appropriate tests methods should be developed by the registrant in consultation with the Agency. The following are offered for guidance.

(1) **Dietary LC50 and no-effect level tests.** Methods for dietary tests may be adapted from the subchronic oral dosing studies for mammals in OPPTS 870.3100 and/or from the avian dietary LC50 study in OPPTS 850.2200.

(2) **Toxicity studies for large and relatively scarce mammals.** An example of an acceptable protocol for toxicity studies with mammals that are large, relatively scarce, or otherwise difficult to obtain is provided as a modification of a protocol that appears in an unpublished draft report to EPA from the American Institute of Biological Sciences (AIBS), titled Analysis of Specialized Pesticide Problems, Volume VI, Wildlife Toxicology Study, pages 4 to 9. This report is dated October, 1974 and was funded under EPA Contract No. 68-01-2457.